Amendments to the claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (original): A sustained release oral solid dosage form for absorption of a therapeutically active medicament in the gastrointestinal tract, comprising:

an effective amount of a medicament having a solubility of less than about 10 g/l to render a therapeutic effect;

a sustained release excipient comprising a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum capable of cross-linking said heteropolysaccharide gum when exposed to an environmental fluid, the ratio of said heteropolysaccharide gum to said homopolysaccharide gum being from about 1:3 to about 3:1; an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1; and a pharmaceutically acceptable cationic cross-linking agent capable of crosslinking with said gelling agent and increasing the gel strength when the dosage form is exposed to an environmental fluid; the ratio of said medicament to said gelling agent being from about 1:3 to about 1:8, said dosage form providing a sustained release of said medicament when exposed to an environmental fluid.

Claim 2. (original): The oral solid dosage form of claim 1, wherein said heteropolysaccharide gum comprises xanthan gum and said homopolysaccharide gum comprises locust bean gum.

Claim 3. (original): The oral solid dosage form of claim 2, wherein said cationic crosslinking agent comprises from about 0.5 to about 16 percent of said formulation, by weight.

Claim 4. (canceled)

Claim 5. (presently amended): The oral solid dosage form of claim ~~4~~1, wherein said medicament is a therapeutically effective dihydropyridine.

Claim 6. (original): The oral solid dosage form of claim 1, wherein said medicament is

selected from the group consisting of nifedipine, nimodipine, nivadipine, nitrendipine, nisolidipine, niludipine, nicardipine and felodipine.

Claim 7. (original): The oral solid dosage form of claim 1, wherein said cationic crosslinking agent comprises an alkali metal or an alkaline earth metal sulfate, chloride, borate, bromide, citrate, acetate, or lactate.

Claim 8. (original): The oral solid dosage form of claim 1, wherein said cationic cross-linking agent comprises calcium sulfate.

Claim 9. (original): The oral solid dosage form of claim 1, which further comprises an effective amount of a pharmaceutically acceptable wetting agent for said medicament.

Claims 10-21 (canceled)

Claim 22. (original): A method of preparing a oral extended release formulation of a medicament having poor solubility in water, comprising:

preparing a sustained release excipient comprising from about 10 to about 99 percent by weight of a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum capable of cross-linking said heteropolysaccharide gum when exposed to an environmental fluid, the ratio of said heteropolysaccharide gum to said homopolysaccharide gum being from about 1:3 to about 3:1, from about 1 to about 20 percent by weight of a cationic crosslinking agent capable of crosslinking with said gelling agent to increase the gel strength when exposed to an environmental fluid, and from about 0 to about 89 percent by weight of an inert pharmaceutical diluent; and

adding an effective amount of a medicament having a solubility of less than about 10 g/l to render a desired therapeutic effect, such that a final product is obtained having a ratio of said medicament to said gelling agent from about 1:3 to about 1:8, such that a gel matrix is created when said formulation is exposed to environmental fluid and said formulation provides therapeutically effective blood levels of said medicament for at least 12 hours.

Claims 23-34 (canceled)

Claim 35. (original): The method of claim 22, wherein said formulation provides therapeutically effective blood levels of said medicament for at least 24 hours.

Claim 36. (original): The method of claim 22, further comprising compressing the mixture of said sustained release excipient and said tablet into tablets.

Claim 37. (original): A sustained release oral solid dosage form for providing an effective dose of nifedipine over a 24 hour period, comprising

a sustained release excipient comprising from about 10 to about 99 percent by weight gelling agent comprising xanthan gum and locust bean gum in a ratio of about 3:1 to about 1:3; from about 0 to about 89 percent by weight of an inert pharmaceutically acceptable diluent selected from the group consisting of a monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and from about 1 to about 20 by weight of a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength; and

from about 20 mg to about 90 mg of nifedipine; said gelling agent, said diluent and said cationic crosslinking agent being granulated with a hydrophobic material selected from the group consisting of an alkylcellulose, an copolymer of acrylic and methacrylic esters, waxes, shellac, zein, hydrogenated vegetable oils and mixtures of any of the foregoing, prior to the incorporation of said dose of nifedipine.

Claim 38 (original): The dosage form of claim 37, further comprising a hydrophobic coating of from about 1 to about 20 percent of the total weight of said tablet, said coating covering at least a portion of the surface of said tablet.

Claims 39-48 (canceled)

Claim 49. (original): A sustained release oral solid dosage form for absorption of a therapeutically active medicament in the gastrointestinal tract, comprising:

an effective amount of a medicament having a solubility of less than about 10 g/l to render a therapeutic effect;

a sustained release excipient comprising a gelling agent, an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1; and

an effective amount of a pharmaceutically acceptable cationic crosslinking agent capable of crosslinking with said gelling agent when exposed to an environmental fluid to increase the gel strength, the ratio of said medicament to said gelling agent being from about 1:3 to about 1:8, said dosage form providing a therapeutically effective blood levels of said medicament for at least about 12 hours.

Claims 50-54 (canceled)

Claim 55. (original): A method of treating a patient with nifedipine, comprising,

preparing a sustained release excipient comprising from about 10 to about 99 percent by weight of a gelling agent comprising xanthan gum and locust bean gum in a ratio of from about 1:3 to about 3:1, from about 1 to about 20 percent by weight of a cationic cross-linking agent, and from about 0 to about 89 percent by weight of an inert pharmaceutical filler;

adding an effective amount of nifedipine to render a desired therapeutic effect;

tableting the resultant mixture such that a final product is obtained having a ratio of said medicament to said gelling agent from about 1:3 to about 1:8, such that a gel matrix is created when said tablet is exposed to gastrointestinal fluid and said tablet provides therapeutically effective blood levels of said medicament; and

administering said tablet to a patient at a predetermined dosage interval from about 12 to about 24 hours.

Claims 56-58 (canceled)

Claim 59. (original): A sustained release oral solid dosage form for absorption of a therapeutically active medicament in the gastrointestinal tract, comprising:

an effective amount of a medicament having a solubility of less than about 10 g/l to render a therapeutic effect; and

a sustained release excipient comprising a gelling agent, an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1, said gelling agent and said inert pharmaceutical diluent being granulated with a hydrophobic material selected from the group consisting of an alkylcellulose, a hydrophobic cellulosic material, a copolymer of acrylic and methacrylic acid esters, shellac, waxes, zein and mixtures of any of the foregoing, prior to the incorporation of said medicament, said hydrophobic material being included in an amount effective to slow the hydration of said gelling agent when said dosage form is exposed to an environmental fluid.

Claim 60. (original): The sustained release oral solid dosage form of claim 59, wherein said gelling agent comprises xanthan gum and locust bean gum in a ratio from about 1:3 to about 3:1.

Claims 61-66 (canceled)

Claim 67. (original): A sustained release excipient, comprising:

a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum which cross-links with said heteropolysaccharide gum when exposed to a fluid in an environment of use, the ratio of said heteropolysaccharide gum to said homopolysaccharide gum being from about 1:3 to about 3:1;

an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1; and

a pharmaceutically acceptable cationic cross-linking agent capable of crosslinking with said gelling agent when exposed to an environmental fluid.

Claims 68-71 (canceled)

Claim 72. (original): A sustained release excipient comprising:

a sustained release excipient comprising from about 10 to about 99 percent by weight gelling agent, from about 0 to about 89 percent by weight of an inert pharmaceutically acceptable diluent selected from the group consisting of a monosaccharide, a disaccharide, a

polyhydric alcohol, and mixtures thereof, and from about 1 to about 20 by weight of a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength.

Claims 73-76 (canceled)

Claim 77. (original) The sustained release excipient, comprising:

a gelling agent;

an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1;

said gelling agent and said inert pharmaceutical diluent being granulated with a hydrophobic material selected from the group consisting of an alkylcellulose, a hydrophobic cellulosic material, a copolymer of acrylic and methacrylic acid esters, shellac, waxes, zein and mixtures of any of the foregoing, prior to the incorporation of said medicament, said hydrophobic polymer being included in an amount effective to slow the hydration of said gelling agent when said dosage form is exposed to a fluid in an environment of use.

Claims 78-80 (canceled)

Claim 81. (original): A method for preparing a sustained release oral solid dosage form for a drug having a solubility of less than about 10 g/l, comprising

preparing a sustained release excipient comprising a gelling agent and a cationic crosslinking agent in an amount effective to cross-link said gelling agent when said gelling agent is exposed to fluid in an environment of use;

preparing a granulate of an effective amount of a medicament having a solubility of less than about 10 g/l with a pharmaceutically acceptable wetting agent, mixing said wetted medicament with said sustained release excipient;

coating said granulate with a hydrophobic material to a weight gain from about 1% to about 20%; and

preparing an oral solid dosage form suitable for human consumption by compressing an appropriate amount of said coated granulate into a tablet, or by incorporating an appropriate amount of said coated granulate into a gelatin capsule.